Supreme Court, U.S.
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No. 97-26

In The Supreme Court Of The United States

OCTOBER TERM 1997

DEBORAH EDDY AND THOMAS EDDY,

Petitioners,

v.

POLYMER TECHNOLOGY CORPORATION, THRIFT DRUG, INC. AND DR. JAMES H. LETHAM, O.D.,

Respondents.

On Petition For A Writ Of Certiorari To The Superior Court Of Pennsylvania

BRIEF OF RESPONDENTS POLYMER TECHNOLOGY CORPORATION AND THRIFT DRUG, INC. IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

KERRY A. KEARNEY
REED SMITH SHAW & McCLAY LLP
435 Sixth Avenue
Pittsburgh, Pennsylvania 15219
(412) 288-3046

Counsel of Record for Respondents Polymer Technology Corporation and Thrift Drug, Inc.

LANTAGNE LEGAL PRINTING
801 East Main Street Suite 100 Richmond, Virginia 23219 (800) 847-0477

QUESTION PRESENTED

I.

Is a tort claim preempted under 21 U.S.C. § 360k of the Medical Device Amendments to the federal Food, Drug and Cosmetics Act where Petitioners' only claimed product defect is that the labeling required by the Food and Drug Administration ("FDA") for a Class III pre-market approved ("PMA") device allegedly makes the product unsafe and defective?

PARTIES TO THE PROCEEDING

The parties to the proceeding below were the Petitioners Deborah Eddy and Thomas Eddy and the Respondents Polymer Technology Corporation, Thrift Drug, Inc., and Dr. James H. Letham, O.D.

RULE 29.6 LISTING

Bausch & Lomb, Incorporated is the parent corporation of Polymer Technology Corporation. Thrift Drug, Inc. is a subsidiary of J.C. Penney Company, Inc. Neither Polymer Technology Corporation nor Thrift Drug, Inc. has any nonwholly owned subsidiaries.

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STATEMENT OF THE CASE

The contact lens cleaning products at issue in this case, Boston Advance® Conditioning Solution ("Solution") and Boston Advance® Cleaner ("Cleaner") are classified as Class III pre-market approved ("PMA") medical devices by FDA. Both are manufactured by Polymer Technology Corporation ("Polymer"). As part of the approval process for the Cleaner and Solution, FDA referred Polymer's PMA application to the FDA's Ophthalmic Devices Panel of the Center of Devices and Radiologic Health for review of labeling by experts in ophthalmology. FDA granted pre-market approval, finding the products safe and effective with certain FDA-approved labeling. Reproduced Record ("R.") 44a. The FDA-approved labeling for the Cleaner instructed the user to "remove all traces of Boston Advance Cleaner by thoroughly rinsing with fresh tap water." R. 49a. The approved instructions for the Solution directed the user to "rinse thoroughly with fresh tap water, then place lenses in storage case and fill the case with Boston Advance Conditioning Solution." R. 45a, 52a.

On September 21, 1992, Petitioners Deborah and Thomas Eddy filed suit in Allegheny County, Pennsylvania against the prescribing

optometrist, Polymer and Thrift Drug, Inc. ("Thrift"). Petitioners claimed that the Solution and Cleaner were defective only because the labeling instructs the user to employ "tap water rinsing:"

> Plaintiffs claim a defect in the product directions and instructions for use . . . which direct and instruct the user "to remove all traces of cleaner by thoroughly rinsing with fresh tap water" without identifying tap water as a potential source of contamination; and in failing to adequately inform or warn users of the risk of contamination from the use of tap water to rinse the lenses.

Petitioners' Complaint at ¶¶ 14(g)-(h). R. 8a.

Deborah Eddy alleges that she developed an acanthamoeba eye infection because she rinsed her lenses in contaminated tap water. Petitioners' claims are based on theories of negligence, strict liability and breach of implied warranty.

Under Section 360k(a) of the Medical Device Amendments to the Food, Drug and Cosmetics Act ("MDA"), state claims are preempted where the claim imposes "requirements" different than or in addition to FDA requirements governing the

manufacture, labeling and distribution of a medical device. 21 U.S.C. § 360k(a) provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -
>
> (1) which is different from, or in addition, to any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

On October 20, 1994, a Pennsylvania trial court granted summary judgment in favor of Respondents Polymer and Thrift, finding that the MDA expressly preempted Petitioners' state tort claims. On December 5, 1995, the Pennsylvania Superior Court affirmed. The Pennsylvania Supreme Court denied Petitioners' request for discretionary review on March 31, 1997.

REASONS FOR DENYING THE WRIT

There is no decision from the Pennsylvania Supreme Court in this case. As a result of the denial, without opinion, by the Pennsylvania Supreme Court of discretionary review, Petitioners and this Court have no basis to know why the Pennsylvania Supreme Court acted. Despite the fact that Petitioners cannot inform this Court of the actual basis for the decision in Eddy v. Polymer, they suggest that an earlier Pennsylvania Supreme Court decision, Green v. Dolsky, 546 Pa. 400, 685 A.2d 110 (1996), cert. denied, 117 S.Ct. 1432 (1997) and 117 S.Ct. 1695 (1997), is in conflict with other state court decisions. Certiorari was denied in Green and review of Green cannot form the basis for grant of Certiorari in this case.

Secondly, review should be denied because the result in Eddy is consistent with Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996). Lohr involved a 510(k) device rather than the Class III PMA device at issue here. Further, in Lohr, there was no FDA "requirement" in conflict with the claimed defect. The Eddy case involves a direct conflict between the defect claimed by Petitioners -- tap water rinsing is dangerous -- and the labeling required by FDA -- tap water rinsing is proper. This case is analogous to a

long line of pre-Lohr preemption cases involving tort claims arising from tampon labeling requirements which culminate with the post-Lohr case, Papike v. Tambrands, Inc., 107 F.3d 737 (9th Cir. 1997). In these tampon warning cases, MDA preemption of failure to warn claims has been found because of a direct conflict between the tampon labeling required by FDA and plaintiff's claimed labeling defect.

A. This Court Should Deny Certiorari Because The Basis Of The Eddy Ruling Is Unknown.

The Pennsylvania Superior Court affirmed the grant of summary judgment in the Eddy case on December 5, 1995, four and a half months before this Court's decision in Medtronic, Inc. v. Lohr. The Pennsylvania Supreme Court denied review without opinion on March 31, 1997, almost one year after Lohr was decided. Polymer and Thrift submit that this Court should not grant Certiorari since this Court cannot know why the Pennsylvania Supreme Court denied review. Clearly, the Pennsylvania Supreme Court had the benefit of Lohr when it denied review in Eddy.

Petitioners suggest that this Court should grant review because the November 22, 1996 Pennsylvania Supreme Court decision in Green v. Dolsky, 546 Pa. 400, 685 A.2d 110 (1996), cert. denied, 117 S.Ct. 1432 (1977) and 117 S.Ct. 1695 (1997), is in conflict with Lohr and with decisions of certain state courts from Arizona, California, Michigan, New York and Illinois. Respondents Polymer and Thrift submit, however, that Green v. Dolsky supplies no basis for review in the Eddy case. Further, Green has already been submitted to this Court for review and Certiorari was denied.

Even if Green were relevant, Petitioners misrepresent the holding of the Pennsylvania Supreme Court in Green v. Dolsky, 546 Pa. 400, 685 A.2d 110 (1996), cert. denied, 117 S.Ct. 1432 (1997) and 117 S.Ct. 1695 (1997). Only certain claims were found preempted for the Class III, PMA device at issue in Green. Other claims were not found preempted by the court in Green. The court in Green undertook a detailed review of Lohr and did not make a wholesale pronouncement that all claims were preempted for PMA devices, despite the Eddy Petitioners' contrary and misleading suggestion to this Court. Clearly, the court in Green found that failure to warn labeling claims were preempted for Class III PMA devices,

although it allowed other claims for PMA devices to proceed to trial.

Polymer and Thrift submit that there is no conflict between Eddy and other state court decisions on preemption since the basis of the Pennsylvania Supreme Court's ruling in Eddy is not known. Further, Green does not stand for the proposition asserted by Petitioners. Green does not find all PMA claims preempted but instead undertakes a careful analysis of Lohr, finding certain claims preempted and others not preempted. This Court should deny the Writ because the basis of decision in Eddy is not known.

B. The Result In The Eddy Case Is Consistent With This Court's Reasoning In Medtronic, Inc. v. Lohr.

To determine whether 28 U.S.C. § 360k invalidates the Eddy product liability claim, a court must determine (1) whether the Eddys' Complaint would establish "requirements" relating to the safety and effectiveness of the contact lens Solution and Cleaner; (2) whether there is an FDA requirement applicable to the contact lens Solution and Cleaner; and (3) whether the labeling "required" in the Eddy

Complaint is "different from or in addition to" the FDA labeling requirement. In finding no preemption for the Lohr 510(k) device, the Lohr court found that there were no FDA requirements which conflicted with the Lohr Petitioners' claim of product defect.[1]

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1 Respondents Polymer and Thrift submit that the determination by FDA's Ophthalmic Devices Panel that tap water rinsing should be included in the labeling for gas permeable contact lens Solution and Cleaner is a "specific requirement[s] applicable to the particular device under the act." As such, FDA's own regulations clearly demonstrate that the Eddy claim should be preempted under 21 C.F.R. § 808.1(d) which provides:

> (d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other **specific requirements applicable to a particular device under the act**, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. . . .

Emphasis added.

21 C.F.R. § 808.1(d)(1) relied on by the Eddy Petitioners at page 7 of their brief does not apply to the issues raised in Eddy since FDA-mandated labeling (tap water rinsing is proper) does not conflict with any

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Respondents Polymer and Thrift submit that the result in Eddy is consistent with Lohr because Eddy involves the PMA process rather than 510(k) review, because FDA has set a labeling requirement for this Solution and Cleaner, and because the labeling requested by Petitioners (no tap water rinsing) is "different from" and "in addition" to the FDA-required labeling (tap water rinsing proper).

This Court should deny the Writ because Eddy is consistent with Lohr.

C. The Result In Eddy Is Consistent With And Not In Conflict With Other Decisions.

The Eddy case involves a direct conflict between FDA requirements and the claimed defect. Petitioners claim only one defect in the contact lens Solution and Cleaner: labeling which permits "tap water rinsing" makes the product unsafe and defective. FDA determined as part of the PMA process that the

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"state or local requirement of general applicability . . ." as required by § 808.1(d)(1).

Solution and Cleaner are "safe and effective" with labeling which instructs the user to employ "tap water rinsing."

Nowhere have Petitioners disputed that the labeling used by Polymer is required by FDA. Joint compliance is impossible. No case decided since Lohr has addressed this narrow issue. Thus, there is no conflict between Eddy and any other decision.

Furthermore, the result in Eddy is consistent with a line of pre-Lohr[2] and post-Lohr cases

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2 The tampon cases decided prior to Lohr include the following, all of which find labeling claims preempted: Moore v. Kimberly-Clark Corp., 867 F.2d 243, 245 (5th Cir. 1989) (affirming grant of summary judgment in favor of tampon manufacturer on plaintiff's failure to warn claim because FDA regulations "outline the liability and warning requirements with respect to TSS") and National Bank of Commerce of ElDorado v. Kimberly-Clark Corp., 38 F.3d 988 (8th Cir. 1994) (tampon warning claims preempted; but finding design and manufacture claims not preempted). Accord Bejarano v. International Playtex, Inc., 750 F. Supp. 443 (D. Idaho 1990); Krause v. Kimberly-Clark Corp., 749 F. Supp. 164 (W.D. Mich. 1990); Northrip v. International-Playtex, Inc., 750 F. Supp. 402 (W.D. Mo. 1989); Lindquist v. Tambrands, Inc., 721 F. Supp. 1058 (D. Minn. 1989); Cornelison v. Tambrands, Inc., 710 F. Supp. 706 (D. Minn. 1989); Meyer v. International Playtex, Inc., 724 F. Supp. 288

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dealing with tampons and the FDA-required toxic shock warning. In Papike v. Tambrands, Inc., 107 F.3d 737 (9th Cir. 1997), plaintiffs claimed that Class II tampons were defective in that they did not provide sufficient warning of the danger of toxic shock syndrome. The Ninth Circuit Court of Appeals in Papike found the claim preempted since Tambrands had provided the label warning required by FDA. The court in Papike determined that preemption was consistent with the U.S. Supreme Court's decision in Lohr because of the specific labeling requirement for tampons.

Respondents submit that this Court should deny the Writ because there is no conflict

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(D.N.J. 1988); Lavetter v. International Playtex, Inc., 706 F. Supp. 722 (D. Ariz. 1988); Rinehart v. International Playtex, Inc., 688 F. Supp. 475 (S.D. Ind. 1988); Edmondson v. International Playtex, Inc., 678 F. Supp. 1571 (N.D. Ga. 1987); Stewart v. International Playtex, Inc., 672 F. Supp. 907 (D.S.C. 1987); Lulov v. Tambrands, Inc., 198 A.D.2d 479, 604 N.Y.S.2d 206 (App. Div. 1993); Poloney v. Tambrands, Inc., 412 S.E.2d 526 (Ga. 1991); Berger v. Personal Prods., Inc., 797 P.2d 1148 (Wash. 1990), cert. denied, 499 U.S. 961 (1991).

between Eddy and a long line of federal court labeling cases dealing with tampons.

D. There Are No Important Issues At Stake In This Case.

This Court should deny review because this case does not present any important issues. The case does not present a basis for review of preemption in the PMA process. [3] This case presents a narrow

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3 Several federal cases have addressed the issue of MDA preemption since the Supreme Court's decision in Lohr. Respondent Polymer and Thrift submit that the result in Eddy is consistent with each of these post-Lohr federal cases. Committee of Dental Amalgam Mfrs. and Distribs. v. Stratton, 92 F.3d 807 (9th Cir. 1996) (no preemption for Class I and Class II devices), cert. denied, 117 S.Ct. 754 (1997); Duvall v. Bristol-Myers-Squibb Co., 103 F.3d 324 (4th Cir. 1996) (on remand from U.S. Supreme Court, no preemption for Class III penile implant approved by FDA through 510(k) substantial equivalence review, even though device was tested through IDE process prior to submission of the 510(k) notification); Feldt v. Mentor Corp., 95 F.3d 4 (5th Cir. 1996) (on remand from the U.S. Supreme Court, no MDA preemption for Class III 510(k) device); Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090 (6th Cir. 1997), cert. filed, 65 U.S.L.W. 3755 (May 1, 1997) (on remand from the U.S. Supreme Court, affirming summary judgment based on MDA preemption for Class III pacemaker reviewed through

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issue dealing with a direct conflict between FDA-required labeling and the labeling defect claimed by Petitioners.

Because this case was decided by an intermediate appellate court in Pennsylvania without the benefit of any decision by the highest court of the state, because it involves a narrow issue and because it is consistent with all post-Lohr federal

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the IDE process where components of the product were submitted to FDA through the 510(k) substantial equivalence review); Reeves v. AcroMed Corp., 103 F.3d 442 (5th Cir. 1997) (on remand from the United States Supreme Court, finding no preemption for Class III metal bone implant submitted to FDA through 510(k) substantial equivalence review.) See Berish v. Richards Med. Co., 937 F. Supp. 181 (N.D. N.Y. 1996) (finding MDA preemption for all claims for Class III IDE hip prosthesis, except claims for failure to follow FDA regulations); Niehoff v. Surgidev Corp., 1997 WL 336346 (D. Ky. June 19, 1997).

decisions, there is no important federal issue raised in this case sufficient to justify the grant of Certiorari.[4]

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[4] In the absence of federal court precedent on an issue dealing with the interpretation of federal law, Petitioners suggest that this Court should find a conflict based on state court decisions from Illinois (in the Seventh Circuit); Arizona (in the Ninth Circuit); California (in the Ninth Circuit); New York (in the Second Circuit); Florida (in the Eleventh Circuit) and Michigan (in the Sixth Circuit). See state court cases cited by Eddy Petitioners at pages 4, 5 of their brief. While the Supreme Court rules theoretically permit the assertion of such a conflict, Respondents Polymer and Thrift submit that this Court should deny Certiorari until the federal courts of appeal in which these states are located have looked at the issue of MDA preemption for Class III PMA Devices. With the exception of the Ninth Circuit, none of these circuits have looked at MDA preemption for PMA Class III devices. The pre-Lohr Ninth Circuit decision in Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995) finds no MDA preemption for claims relating to a Class III PMA device, finding for the product at issue there were no FDA "requirements." The Kennedy Court, however, specifically approves the tampon cases in which a specific FDA-required label can support a finding of MDA preemption. Further, the Ninth Circuit in the post-Lohr tampon warning case, Papike, supra, cites Kennedy with approval. The result in Eddy is absolutely consistent with the Ninth Circuit law set forth in Kennedy and Papike, since in Eddy there is a "specific requirement applicable to the particular device." This Court should deny Certiorari based on conflicts set forth in state court decisions since

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CONCLUSION

Respondents Polymer and Thrift submit that the Petition for Writ of Certiorari should be denied.

Respectfully submitted,

Kerry A. Kearney
REED SMITH SHAW & McCLAY LLP
James H. Reed Building
435 Sixth Avenue
Pittsburgh, Pennsylvania 15219
(412) 288-3046

Counsel for Respondents
Polymer Technology Corporation
and Thrift Drug, Inc.

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this important federal issue has not been ruled on by federal courts of appeal.